



**PATENT**  
Attorney Docket No. 224559

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Application of:

Boehm et al.

Application No. 10/667,570

Filed: September 22, 2003

Art Unit: Unassigned

Examiner: Unassigned

For: SUSTAINED RELEASE OPIOID  
FORMULATIONS AND METHOD OF  
USE

**INFORMATION DISCLOSURE STATEMENT**

Mail Stop  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313

Pursuant to 37 CFR 1.97 and 1.98, the references listed on the enclosed Form PTO-1449 and/or Substitute Form PTO-1449 ("Form 1449") are submitted for consideration by the Examiner in the examination of the above-identified patent application.

The full consideration of the references in their entirety by the Examiner is respectfully requested and encouraged. Also, it is respectfully requested that the references be entered into the record of the present application and that the Examiner place his or her initials in the appropriate area on the enclosed Form 1449, thereby indicating the Examiner's consideration of each of the references.

The submission of the references listed on the Form 1449 is for the purpose of providing a complete record and is not a concession that the references listed thereon are prior art to the invention claimed in the patent application. The right is expressly reserved to establish an invention date earlier than the above-identified filing date in order to remove any reference submitted herewith as prior art should it be deemed appropriate to do so.

Further, the submission of the references is not to be taken as a concession that any reference represents art that is relevant or analogous to the claimed invention. Accordingly, the right to argue that any reference is not properly within the scope of prior art relevant to an examination of the claims in the above-identified application is also expressly reserved.

The Information Disclosure Statement is being filed:

- ☒ **within** any one of the following time periods: (a) within three months of the filing date of a national application other than a continued prosecution application under 37 CFR 1.53(d); (b) within three months of the date of entry of the national stage as set forth in 37 CFR 1.491 of an international application; (c) before the mailing date

of a first Office Action on the merits; or (d) before the mailing of a first Office Action after the filing of a request for continued examination under 37 CFR 1.114.

- ☐ **after** (a), (b), (c) or (d) above, but before the mailing date of a final action under 37 CFR 1.113, a Notice of Allowance under 37 CFR 1.311, or an action that otherwise closes prosecution in the application, and includes *one* of:

☐ the Statement under 37 CFR 1.97(e) (see "Statement under 37 CFR 1.97(e)" below).

*or*

☐ the fee of \$180 set forth in 37 CFR 1.17(p) (see "Fees" below).

- ☐ **after** the mailing date of a final action under 37 CFR 1.113 or a Notice of Allowance under 37 CFR 1.311, or an action that otherwise closes prosecution in the application, and on or before payment of the issue fee, and includes the Statement under 37 CFR 1.97(e) (see "Statement under 37 CFR 1.97(e)" below), and the fee of \$180 as set forth in 37 CFR 1.17(p) (see "Fees" below).

- ☐ **after** the mailing date of a Notice of Allowance under 37 CFR 1.311, and on or before payment of the issue fee, and **within** thirty days of receiving each item of information contained in the Information Disclosure Statement, and includes the Statement under 37 CFR 1.704(d) (see "Statement under 37 CFR 1.704(d)" below), and the fee of \$180 as set forth in 37 CFR 1.17(p) (see "Fees" below).

NOTE: This is for original applications except applications for a design patent, filed on or after May 29, 2000, wherein a paper containing only an Information Disclosure Statement in compliance with 37 CFR 1.97 and 1.98 is being filed.

### Copies of the References

- ☐ Copies of the references listed on the enclosed Form 1449 are enclosed herewith. Attached to each reference not in the English language is a concise explanation of the relevance pursuant to 37 CFR 1.98(a)(3). An English-language equivalent/patent, or an English-language abstract, or an English-language version of the search report or action by a foreign patent office in a counterpart foreign application indicating the degree of relevance found by the foreign office is being submitted in lieu of a concise explanation of the relevance pursuant to 37 CFR 1.98(a)(3).

- ☐ A copy of the foreign search report is enclosed herewith.

- ☐ The references listed on the enclosed Form 1449 were previously identified in the parent application(s) of the present application, and copies of the references were furnished at that time. Accordingly, additional copies of the references are not submitted herewith, so as not to burden the file with duplicate copies of references. The Examiner is respectfully requested to carefully review the references in accordance with the requirements set out in the Manual of Patent Examining Procedure. In accordance with 37 CFR 1.98(d), the details of the parent application(s) relied upon for an earlier filing date under 35 USC 120 in which copies of the references were previously furnished are set out below:

In re Appln. of: Boehm et al.  
Application No.: 10/667,570

U.S. APPLICATIONS		Status ( <i>check one</i> )		
U.S. APPLICATIONS	U.S. FILING DATE	PATENTED	PENDING	ABANDONED
1.				
2.				
3.				

**Statement under 37 CFR 1.97(e)**

- ☐ The **undersigned** hereby states that each item of information contained in the Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign patent application not more than three months prior to the filing of the Information Disclosure Statement.
- ☐ The **undersigned** hereby states that no item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign patent application, and, to the knowledge of the undersigned after making reasonable inquiry, no item of information contained in the Information Disclosure Statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the Information Disclosure Statement.

**Statement under 37 CFR 1.704(d)**

- ☐ The **undersigned** hereby states that each item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart application and that this communication was not received by any individual designated in 37 CFR 1.56(c) more than thirty days prior to the filing of the Information Disclosure Statement.

**Fees**

- ☒ No fee is owed by the applicant(s).
- ☐ The **IDS Fee of \$180** under 37 CFR 1.17(p) is enclosed herewith.

**Method of Payment of Fees**

- ☐ Attached is a check in the amount of \$ .
- ☐ Charge Deposit Account No. 12-1216 in the amount of \$ . (A duplicate copy of this communication is enclosed for that purpose.)


**Authorization to Charge Additional Fees**

- ☒ If any additional fees are owed in connection with this communication, please charge Deposit Account No. 12-1216. (A duplicate copy of this communication is enclosed for that purpose.)

In re Appln. of: Boehm et al.  
Application No.: 10/667,570

**Instructions as to Overpayment**

☒ Credit Account No. 12-1216.  
☐ Refund

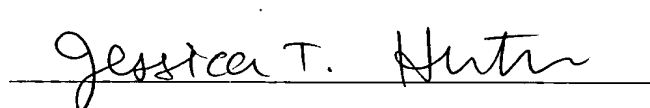
  
Jeremy C. Lowe, Reg. No. 48,085  
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Date: December 22, 2003

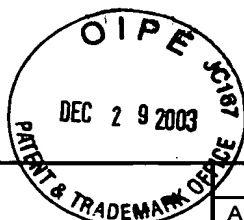
**CERTIFICATE OF MAILING**

I hereby certify that this INFORMATION DISCLOSURE STATEMENT (along with any documents referred to as being attached or enclosed) is being deposited with the United States Postal Service on the date shown below with sufficient postage as first class mail in an envelope addressed to: Mail Stop, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313.

Date: 12/22/03

  
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Substitute for form 1449A/B/PTO

# **INFORMATION DISCLOSURE STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

**Complete if Known**

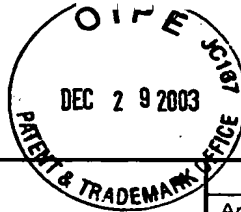
Application Number	10/667,570
Filing Date	September 22, 2003
First Named Inventor	Garth Boehm
Group Art Unit	Unassigned
Examiner Name	Unassigned
Attorney Docket Number	224559

Sheet 1 of 4

## **U.S. PATENT DOCUMENTS**

Examiner Initials	Doc. No.	U.S. Patent Document		Name of Patentee or Applicant	Date of Publication	Filing Date If Appropriate
		Application or Patent Number	Kind Code			
	AA	2001/0002259	A1	Reder et al.	05/31/01	01/08/01
	AB	2001/0008639	A1	Oshlack et al.	07/19/01	02/16/01
	AC	2001/0019725	A1	Miller et al.	09/06/01	12/19/00
	AD	2001/0031278	A1	Oshlack et al.	10/18/01	04/05/01
	AE	2001/0033865	A1	Oshlack et al.	10/25/01	07/22/99
	AF	2001/0036476	A1	Oshlack et al.	11/01/01	02/06/01
	AG	2001/0036477	A1	Miller et al.	11/01/01	03/06/01
	AH	2001/0038853	A1	Kendrup et al.	11/08/01	03/29/01
	AI	2001/0038858	A1	Roser et al.	11/08/01	01/05/01
	AJ	2002/0006438	A1	Oshlack et al.	01/17/02	09/25/98
	AK	2002/0010127	A1	Oshlack et al.	01/24/02	02/08/01
	AL	2002/0013301	A1	Kaiko et al.	01/31/02	03/22/01
	AM	2002/0015730	A1	Hoffmann et al.	02/07/02	02/27/01
	AN	2002/0018810	A1	Oshlack et al.	02/14/02	08/20/01
	AO	2002/0039594	A1	Unger	04/04/02	05/11/98
	AP	2002/0044962	A1	Cherukuri et al.	04/18/02	10/19/01
	AQ	2002/0058050	A1	Sackler et al.	05/16/02	09/26/97
	AR	2002/0058673	A1	Kaiko et al.	05/16/02	11/05/01
	AS	2002/0081333	A1	Oshlack et al.	06/27/02	06/26/01
	AT	2002/0102300	A1	Miller et al.	08/01/02	02/05/02
	AU	2002/0102302	A1	Oshlack et al.	08/01/02	10/19/01
	AV	2002/0102303	A1	Oshlack et al.	08/01/02	02/04/02
	AW	2002/0106408	A1	Bacon et al.	08/08/02	12/01/00
	AX	2002/0106410	A1	Masters	08/08/02	12/11/01
	AY	2002/0110595	A1	Chang et al.	08/15/02	01/11/02
	AZ	2002/0110596	A1	Fanara et al.	08/15/02	01/28/02
	BA	2002/0155156	A1	Mulye	10/24/02	04/18/02
	BB	2003/0190358	A1	Oshlack et al.	10/09/03	09/12/02
	BC	4,590,068	B1	Berthet et al.	05/20/86	
	BD	4,729,904	B1	Berthet et al.	03/08/88	
	BE	4,762,709	B1	Sheumaker	08/09/88	
	BF	4,780,322	B1	Martani et al.	10/25/88	
	BG	4,786,503	B1	Edgren et al.	11/22/88	
	BH	4,795,641	B1	Kashdan	01/03/89	
	BI	4,801,460	B1	Goertz et al.	01/31/89	
	BJ	4,834,965	B1	Martani et al.	05/30/89	
	BK	4,834,984	B1	Goldie et al.	05/30/89	
	BL	4,844,909	B1	Goldie et al.	07/04/89	
	BM	4,861,598	B1	Oshlack	08/29/89	
	BN	4,874,613	B1	Hsiao	10/17/89	
	BO	4,894,239	B1	Nonomura et al.	01/16/90	
	BP	4,952,402	B1	Sparks et al.	08/28/90	
	BQ	4,959,219	B1	Chow et al.	09/25/90	
	BR	4,990,341	B1	Goldie et al.	02/05/91	
	BS	4,996,047	B1	Kelleher et al.	02/26/91	
	BT	5,004,613	B1	Radebaugh et al.	04/02/91	

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Substitute for form 1449A/B/PTO

# **INFORMATION DISCLOSURE STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Sheet

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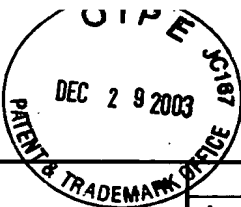
## **Complete if Known**

Application Number	10/667,570
Filing Date	September 22, 2003
First Named Inventor	Garth Boehm
Group Art Unit	Unassigned
Examiner Name	Unassigned
Attorney Docket Number	224559

## **U.S. PATENT DOCUMENTS**

Examiner Initials	Doc. No.	U.S. Patent Document		Name of Patentee or Applicant	Date of Publication	Filing Date If Appropriate
		Application or Patent Number	Kind Code			
	BU	5,073,380	B1	Babu et al.	12/17/91	
	BV	5,133,974	B1	Paradissis et al.	07/28/92	
	BW	5,143,661	B1	Lawter et al.	09/01/92	
	BX	5,202,128	B1	Morella et al.	04/13/93	
	BY	5,240,963	B1	Domb et al.	08/31/93	
	BZ	5,266,331	B1	Oshlack et al.	11/30/93	
	CA	5,273,760	B1	Oshlack et al.	12/28/93	
	CB	5,286,493	B1	Oshlack et al.	02/15/94	
	CC	5,288,503	B1	Wood et al.	02/22/94	
	CD	5,321,012	B1	Mayer et al.	06/14/94	
	CE	5,330,766	B1	Morella et al.	07/19/94	
	CF	5,378,474	B1	Morella et al.	01/03/95	
	CG	5,394,626	B1	Brown	03/07/95	
	CH	5,395,626	B1	Kotwal et al.	03/07/95	
	CI	5,409,711	B1	Mapelli et al.	04/25/95	
	CJ	5,411,745	B1	Oshlack et al.	05/02/95	
	CK	5,445,829	B1	Paradissis et al.	08/29/95	
	CL	5,460,826	B1	Merrill et al.	10/24/95	
	CM	5,462,747	B1	Radebaugh et al.	10/31/95	
	CN	5,472,712	B1	Oshlack et al.	12/05/95	
	CO	5,474,786	B1	Kotwal et al.	12/12/95	
	CP	5,478,577	B1	Sackler et al.	12/26/95	
	CQ	5,500,227	B1	Oshlack et al.	03/19/96	
	CR	5,508,042	B1	Oshlack et al.	04/16/96	
	CS	5,508,043	B1	Krishnamurthy	04/16/96	
	CT	5,518,730	B1	Fuisz	05/21/96	
	CU	5,520,931	B1	Persson et al.	05/28/96	
	CV	5,529,787	B1	Merrill et al.	06/25/96	
	CW	5,549,912	B1	Oshlack et al.	08/27/96	
	CX	5,556,838	B1	Mayer et al.	09/17/96	
	CY	5,580,578	B1	Oshlack et al.	12/03/96	
	CZ	5,591,452	B1	Miller et al.	01/07/97	
	DA	5,593,695	B1	Merrill et al.	01/14/97	
	DB	5,601,842	B1	Bartholomaeus	02/11/97	
	DC	5,614,218	B1	Olsson et al.	03/25/97	
	DD	5,639,476	B1	Oshlack et al.	06/27/97	
	DE	5,645,858	B1	Kotwal et al.	07/08/97	
	DF	5,656,291	B1	Olsson et al.	08/12/97	
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	DI	5,672,360	B1	Sackler et al.	09/30/97	
	DJ	5,681,585	B1	Oshlack et al.	10/28/97	
	DK	5,702,725	B1	Merrill et al.	12/30/97	
	DL	5,780,055	B1	Habib et al.	07/14/98	
	DM	5,811,126	B1	Krishnamurthy	09/22/98	
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Substitute for form 1449A/B/PTO

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Sheet 3 of 4

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		Application or Patent Number	Kind Code			
	DO	5,849,240	B1	Miller et al.	12/15/98	
	DP	5,879,705	B1	Heafield et al.	03/09/99	
	DQ	5,891,471	B1	Miller et al.	04/06/99	
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	DS	5,952,005	B1	Olsson et al.	09/14/99	
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	DY	5,968,551	B1	Oshlack et al.	10/19/99	
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	EA	6,001,392	B1	Wen et al.	12/14/99	
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	EF	6,077,533	B1	Oshlack et al.	06/20/00	
	EG	6,077,538	B1	Merrill et al.	06/20/00	
	EH	6,103,261	B1	Chasin et al.	08/15/00	
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	EJ	6,143,322	B1	Sackler et al.	11/07/00	
	EK	6,143,328	B1	Heafield et al.	11/07/00	
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	ES	6,245,351	B1	Nara et al.	06/12/01	
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	EU	6,248,363	B1	Patel et al.	06/19/01	
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	FA	6,297,286	B1	Huckle	10/02/01	
	FB	6,306,438	B1	Oshlack et al.	10/23/01	
	FC	6,309,668	B1	Bastin et al.	10/30/01	
	FD	6,316,031	B1	Oshlack et al.	11/13/01	
	FE	6,326,027	B1	Miller et al.	12/04/01	
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	FG	6,372,254	B1	Ting et al.	04/16/02	
	FH	6,399,096	B1	Miller et al.	06/04/02	

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Sheet	4	of	4
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Examiner Initials	Doc. No.	U.S. Patent Document		Name of Patentee or Applicant	Date of Publication	Filing Date If Appropriate
		Application or Patent Number	Kind Code			
	F I	6,436,438	B1	Momberger et al.	08/20/02	
	F J	6,451,350	B1	Bartholomaeus et al.	09/17/02	
	F K	6,451,848	B1	Behl et al.	09/17/02	
	F L	6,572,885	B2	Oshlack et al.	06/03/03	
	F M	6,599,529	B1	Skinhoj et al.	07/29/03	
	F N	6,632,451	B2	Penhasi et al.	10/14/03	

[illegible]

Date Considered

- \* A concise statement of relevance is being submitted in lieu of a translation. 37 CFR 1.98(a)(3).
- + An English-language equivalent/patent, or an English-language abstract, or an English-language version of the search report or action by a foreign patent office in a counterpart foreign application indicating the degree of relevance found by the foreign office is being submitted in lieu of a concise explanation of relevance under 37 CFR 1.98(a)(3).